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Patient Perspectives on Access Control of Electronic Health Records

Polly Okello

Submitted in partial fulfilment of the requirements for the Degree of
Master of Applied Philosophy and Ethics at Strathmore University



Nairobi, Kenya

June, 2019

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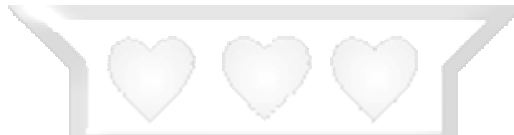
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Polly Okello

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Approval

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Abstract

Recent technological advances pose a challenge to the basic framework of medical ethics and the fundamental nature of the doctor-patient relationship - a relationship based on consent and trust that has stood for almost 2,500 years. Access to health records may be granted, in limited circumstances, for example, to relatives or proxies of incapacitated or deceased patients. Disclosure of patient information for legal or public interest purposes, sharing of health information of people who lack mental capacity, and access to medical information relating to relatives all have ethical implications.

The first objective of the study was to identify patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State. The second objective of the study was to identify the extent to which sensitivity of EHRs is linked to patient-controlled access to their EHRs. The third objective of the study was to investigate the extent to which different situations may affect patients' perspective on access to their EHRs.

This study adopted a mixed study approach in which a multi-site cross-sectional questionnaire was designed and piloted for use in waiting rooms and administered to randomly selected patients ($N=394$) in private doctor clinics in Nairobi, Kenya (in February 2019). These clinics were involved in the pilot of a novel EHRs known as MedbookAfrica. Quantitative data was analysed using Statistical Package for Social Sciences (SPSS) while qualitative data was analysed thematically.

A vast majority of patients ($>70\%$) agreed that they have the right to grant or deny access to their EHR irrespective of the recipient or sensitivity. A vast majority also agreed that in emergencies, incapacitation or death, their health record should be made accessible. The interviews revealed that the recipients of the health record in case of emergency or incapacitation should be limited to close family members or primary doctor. The interviews also revealed that patients perceive their electronically stored health records to be safe.

Patients expressed sharing preferences consistent with a desire to exercise autonomy over which health information is shared and with whom. Close family members and primary

doctor were people that the patients felt should have access to their health records to assist in treatment and especially in emergency situations.

The study recommended that a level of informed consent needs to be factored in during EHR design to protect patient autonomy and conditions when this can be overridden to be agreed upon by all stakeholders. An open dialogue between patients and health care providers is required to balance respect for patient autonomy and the health care provider's need for patient information to provide good quality care.



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List of Abbreviations

AMA	American Medical Association
CAK	Communications Authority of Kenya
CIOMS	Council for International Organizations of Medical Sciences
EHR	Electronic Health Record
GCP	Good Clinical Practice
HHS	The United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
ICT	Information and Communication Technology
IDSR	Integrated Disease Surveillance and Response
IRB	Institutional Review Board
KDHS	Kenya Demographic and Health Survey
KNBS	Kenya National Bureau of Statistics
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
PHI	Personal Health Information
PHR	Personal Health Record
SCR	Summary Use Service
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
UN	United Nations
US	United States

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CHAPTER ONE: INTRODUCTION

1.1 Introduction

This chapter gives a background to the study, current legal framework in Kenya pertaining to Electronic Health Records (EHRs), the problem statement, objectives of the study, research questions, significance and justification of the study, scope and limitations of the study.

1.2 Background to the Study

The practice of making notes about patient encounters dates to Hippocrates in the fifth century BCE. The early twentieth century saw the invention of the first programmable computers leading to a move towards computerizing health. Technological advances pose a challenge to the basic framework of medical ethics and the fundamental nature of the doctor-patient relationship - a relationship based on consent and trust. This is because interoperable Electronic Health Records systems (EHRs) create new, more powerful means of access to patients' health information. Given potential access by several layers of entities with access to patient health information, such as government authorities, insurance companies, employers and researchers, lack of access control by patients poses an additional privacy concern (Cushman, R., Froomkin, A. M., Cava, A., Abril, P., & Goodman, K. W. (2010). Secondary uses of patient health data include quality improvement, research, public safety, and public health. In so far as these uses may have impressive benefits, each raises critical issues for patient trust (Safran et al., 2007).

Unauthorized access of a patient's sensitive medical information such as mental illness, Human Immunodeficiency Virus (HIV) infection, sexually transmitted disease, genetic disorders, or mental illness may cause stigmatization, emotional stress, embarrassment, marital problems, reputation loss, and loss of a job or insurance. These all have possible serious ethical implications. If patients feel that their health information is not private, they may engage in "privacy-protecting behaviors" such as changing doctors, paying cash for consultations, requesting a doctor to omit certain information from their

medical record, providing inaccurate medical history or not seeking medical care. This can adversely affect the quality of care given to the patient and can cause harm to them because the doctor may use inaccurate or misleading information (Cushman et al., 2010). Any medical research based on inaccurate EHRs data can lead to erroneous conclusions that can have adverse effects on public health policies (Scott, 2000).

If a patient has full mental capacity, is fully informed and voluntarily and explicitly consents to disclosure, a doctor is relieved from the duty of confidence. However, this can have ethical implications in a critical care setting when patients are sedated or unconscious or are incapacitated because of a mental illness making it impractical to obtain consent. In such cases, it may be unethical to withhold information from a next-of-kin as it may be detrimental to the patient's best interests and any decision made on behalf of a patient should be done proportionately and in their best interests. In a hospital setting, where a multi-disciplinary team is taking care of a patient, the ethical implication of non-disclosure of relevant facts is potential poor-quality management with resultant harm to the patient. If medical students and nurses have access to patient records as part of their training, they are expected to maintain patient confidentiality (Blightman, K., Griffiths, S. E., & Danbury, C. (2013).

Disclosure in vulnerable populations, such as the young and elderly, raises ethical concerns. Children may wish to withhold sensitive health information from their parents and in the UK, a mature minor's right to confidentiality is permitted when it is deemed to be in their best interests. However, the doctor has a duty to persuade the child to inform their parent or request permission to do so. The ethical implication of maintaining confidentiality in such cases arises when there is suspected child abuse. Similarly, an elderly patient might have impairments that reduce his/her ability to make informed judgments about their health data collection and sharing (Cushman et al., 2010).

If a patient's health information is required by law, the doctor is obliged to avail the required information. An example is a case where a police officer requests a blood alcohol sample to be taken from an unconscious accident victim, unable to give consent, as part of an investigation. If there is a court order requiring the sample to be taken or an overriding public interest in disclosure of such information, then it may be unethical

for the doctor to refuse. Coroners can request medical details about a patient especially if there is suspicion of violent or unnatural death or the cause of death is undetermined. In such circumstances, there would be ethical implications if such relevant information is withheld by a doctor – this may include justice for the victim, in case of murder for example (Blightman, K., Griffiths, S. E., & Danbury, C. (2013).

Disclosures can also be made in the public interest which ranges from prevention or detection of serious crime to public health. In situations where national security is at risk, for example, terrorism, failure to disclose relevant information may have serious ethical implications because of the threat of harm to potentially many people. In the United States, there is a *prima facie* duty to breach confidentiality and warn a victim, who is identifiable, where there is a risk of harm from a patient. If a serious communicable disease has contributed to a patient's death, withholding such information can have ethical implications to public health. This makes a case for disclosing relevant anonymized information relating to serious communicable disease to relevant authorities. In Kenya, doctors are required to report specific communicable diseases or industrially related disease, governed by the Public Health Act (Cap 242).

In summary, disclosure of patient information for legal or public interest purposes, sharing of health information of people who lack mental capacity, and access to medical information relating to relatives all have ethical implications.

Legal Framework

Constitution of Kenya 2010, Article 31 (Kenia, 2013) provides for the right to privacy. Information that is personal or capable of individually identifying a person is confidential and should not be unnecessarily requested or disclosed. Article 35 provides for the right of Access to Information, which entitles patients to access their own EHRs and any other relevant information that would affect them. Article 24 provides that a right or fundamental freedom in the Bill of rights shall not be limited except by law. Articles 24, 31 and 35 are in Chapter 4 of the Bill of Rights.

Medical Practitioners and Dentists Act Cap 253 provides for the *Medical Practitioners and Dentists Board (Disciplinary Proceedings) (Procedure) Rules* which prohibit abuse of professional confidence. Rule 8 provides that a practitioner or an institution shall not disclose to third party information which has been obtained in confidence from a patient. The only exceptions that exist for the disclosure of information rule include where information is released for valid governmental and public interest reasons, required by a court order or with the patient's knowledge or consent.

The guiding principles of *The Health Information System Policy* include the availability of health information as a public good, recognition of the right to privacy, promotion of ethical considerations in relation to data security, information sharing and establishment of linkages using appropriate technologies.

Section 1 of *Standards and Guidelines for Electronic Medical Record Systems in Kenya* sets guidelines which any software used by health care providers in EHRs are required to meet. Section 2 deals comprehensively with interoperability of health systems.

The current *Health Bill* and the *Health Records and Information Managers Bill* seek to provide the legal backing for the use of EHRs in Kenya. *Kenya Information & Communication Act* as amended by the *Kenya Information and Communication (Amendment) Act 2013* provide general guidelines for handling electronic information. Section 83Q provides that the Information and Communication Technology (ICT) Minister may by notification in the Gazette, declare that any computer system or network is a protected system and any person who seeks to access such system must seek authorization. It is an offence for an unauthorized person to access a protected system.

1.3 Statement of Problem

Whether and to what extent it is ethical for patients to control access to all or part of their Electronic Health Record (EHR).

1.4 Aims and Objectives

1.4.1 Aim of the Study

The purpose of this research is to use digital data technology to improve patient health.

1.4.2 Objectives of the Study

1. To identify patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State.
2. To identify the extent to which sensitivity of EHRs may be linked to patient-controlled access to their EHRs.
3. To investigate the extent to which different situations may affect patients' perspective on access to their EHRs.

1.4.3 Research Questions

1. What are patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State?
2. To what extent is sensitivity of EHRs linked to patient-controlled access to their EHRs?
3. To what extent is patient-controlled access to their EHRs situational?

1.5 Significance and Justification of the Study

An important justification of enabling patient-controlled access is to respect patient autonomy and ensure privacy and confidentiality of their EHR. When a patient chooses to deny different medical practitioners access to his medical records, it may have ethical implications as it may adversely affect his health or life. The health of the society, in general, must also be guaranteed, for example, access to medical records by relevant authorities may allow quick action to be taken in cases of outbreaks of epidemic diseases.

The study gave insight into patient perspectives regarding access control, consent and health records sharing. This study may provide a basis for future law in Kenya concerning ethical implementation of EHRs ensuring patient rights, such as the right to consent in research ethics, are not violated.

1.6 Scope of the study

Data was collected from adult patients attending five private doctor clinics in Nairobi, Kenya. The clinics were specialist clinics including ophthalmology, orthopedics, obstetrics and gynecology. The reason why these clinics were chosen is because these were the clinics where MedbookAfrica, a novel EHR was being piloted. They were varied in terms of medical conditions that patients had. The research participants were over eighteen years of age and this avoided the ethical requirement of engaging with minors, and eased data collection since parental consent was unnecessary.

1.7 Limitations of the Study

This study was carried out in an outpatient setting and not an inpatient setting; the results might differ because of different medical conditions in the patients. This study was carried out in private clinics and not public health facilities; the results may differ because of a likelihood of different socio-demographic characteristics of respondents. The clinics were specialist clinics; though of varied specialities, the specialities were not exhaustive. Hence, the results in other speciality clinics may differ especially if psychiatric or Human Immunodeficiency Virus (HIV) clinics were included due to the more sensitive nature of health records. The study was carried out in an urban city, Nairobi as opposed to a rural setting; reason being that this is where a pilot of an EHRs with patient access control capability was being carried out. Perceptions regarding EHRs may differ in the two settings probably due to different access levels to the internet and ICT. Due to time and budgetary constraints, this research was cross-sectional, taking a 'snapshot' of study participants at the time of the study.

1.8 Conclusion

This chapter gave the background to the study, current legal framework in Kenya pertaining to EHRs, the problem statement, objectives of the study, research questions, significance and justification of the study, scope and limitations of the study.



CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter includes a theoretical review, empirical literature and research gaps. Literature that compares different ethical principles used in health-related decision making is included.

2.2 Theoretical Review

The study of bioethics as ethics applied to life, and specifically to medicine, was born in the late twentieth century. The predominant ethical framework in practical decision-making in medicine has been principlism, proposed by Tom L. Beauchamp and James Childress. Principlism has its foundation in ‘common morality’ defined as a ‘set of moral norms that most cultures already use in practice or agree with’. Its philosophical underpinning is deontological ethics. Deontological ethics, the ethics of duty, aims to establish rules of action. According to Immanuel Kant, the categorical imperative should be the basis of all moral duties. He proposed that all actions should be carried out in such a way that they can become universal laws applicable to all (Beauchamp, T. L., & Childress, J. F. (2001).

Principlism is based on four *prima facie* principles: “(1) Respect for autonomy (a norm of respecting the decision-making capacities of autonomous persons). (2) Nonmaleficence (a norm of avoiding the causation of harm). (3) Beneficence (a group of norms for providing benefits and balancing benefits against risk and costs). (4) Justice (a group of norms for distributing benefits, risks, and costs fairly)” (Beauchamp, T. L., & Childress, J. F. (2001). Relevant to EHRs, a deontological approach protects privacy and confidentiality out of “*respect for persons*, grounded in the fundamental principle of *autonomy*” (Secker, 1999). However, principlism has been criticized for overlooking the moral agent, separating moral decisions from the actor. Also, extreme rationalism has been criticized for its rigidity and ignoring the role of emotions, needs and desires in the decision-making process (Pastura, P. S. V. C., & Land, M. G. P. (2016).

Utilitarianism, in the context of research ethics and EHRs, gives the following argument for maximization of happiness - “given minimal risk to participants, public interest outweighs the participant’s right to autonomy and privacy” (Sutrop, 2011). Utilitarianism is based on maximization of pleasure and utility and targets consequence rather than means – the best consequences for the largest number of people. Utilitarianism is criticized for being a cold, calculating algorithm which does not define what is best, ignores intrinsic value of human beings and their rights (Pastura, P. S. V. C., & Land, M. G. P. (2016).

Virtue ethics or ethics of the good has its roots in the Hippocratic oath (500 BCE). The question shifts from what to do to how to form character to make prudent practical decisions. Virtue ethics places moral worth on the rightness of an action driven by duties and obligations and the goodness of the person who selects such obligations and rules. Human virtue is “a good habit perfecting man in his rational potencies and inclining him to right and perfect use of his potencies” (Gilson, E. (1931). Aristotle’s teleological ethics links virtue with human happiness (*eudaimonia*) which is the highest human good (Nic. Eth. 10.6).

St Thomas Aquinas expanded Aristotle’s theory of morality and defined virtue as “moral excellence based on right action and right thinking, which produce goodness of character” (Aquinas, Thomas. *Treatise on happiness*. University of Notre Dame Press, 1984). For Aquinas, the purpose of virtue is to attain happiness. Aquinas based morality on the Natural Moral Law “built into man’s nature and knowable by reason”. This law is universal and binding to all since reason is radical to man’s nature. (Aquinas, Thomas. *Treatise on happiness*. University of Notre Dame Press, 1984).

The virtuous person follows a moral standard in pursuit of good and rejection of evil (Gardiner, 2003). The virtuous physician must be guided by his obligation to work for a good outcome in the patient-doctor encounter - that which benefits the patient and does not harm him. The ends of medicine are the ends of the patient-doctor encounter – health, cure and care. Virtue and duty are motivators for action, but virtue is more than a stimulus to right action; it is an integral part of character that helps in making right decisions based on what is good (Vizcarrondo, 2012).

In Estonia, a patient's EHR has been modelled in such a way the patient portal allows a patient to view who has accessed their record and when. The portal also allows the patient to declare their position on Do Not Resuscitate (DNR) or organ transplantation. This can be viewed as increasing patient autonomy. Additionally, doctors have a full view of a patient's record to improve efficiency in healthcare delivery. Regarding informed consent, the opt-out approach was preferred to the opt-in whereby patients cannot decide how their record is stored but can decide on who it can be shared with (Sutrop, 2011).

The opt-in model purposes to secure patient privacy over and above the common good and champions explicit informed consent. A utilitarian argument against this model is that it would waste too much time and money. A public interest argument against this model is that managing health care services would be more efficient and research would be more efficient if there was a central database of everyone's medical records. The third argument against the opt-in model is that patients may be ignorant of what is in their best interest and may make wrong choices if allowed to exercise full autonomy. The opt-out model, however, limits autonomy but ensures that anonymous data of most of the population would be available for research or administrative purposes (Sutrop, 2011).

It may be viewed that public interest conflicts with individual rights when these models are interrogated but the result should be a balance between autonomy and common good. If absolutely no consent is sought, patients may be unaware that they have a right, to some extent, of have access to their medical records. Counter to this, according to Estonian law, if a patient denies access to vital health information by their doctor, responsibility of outcome would shift to the patient. Sutrop proposes a practical implementation of patient autonomy that entails education of stakeholders about their rights and obligations that would create a conducive environment for exercising autonomy without deleteriously affecting the common good (Sutrop, 2011).

2.3 Empirical Literature

Health information privacy and security have been debated in the context of electronic databases in healthcare for a long time, but challenges remain on how to implement PHI sharing between health care professionals, researchers and policy makers and maintain patient confidentiality and autonomy. Various surveys have shown that patients are concerned about the security of their electronic health records, but recognise the value of sharing data, both for their own care and for research.

In a study in Toronto, Canada (Tracy, C. S., Dantas, G. C., & Upshur, R. E. (2004), patients expressed mistrust about how their PHI would be used and supported a patient decision aid to improve control over their data. Participants lacked substantial knowledge regarding fate and use of their PHI.

In a hospital based qualitative study in Denmark on patient opinions on EHR use, most patients were positive about use of EHRs in hospitals (Zurita, L., & Nøhr, C. (2004). They expect that their privacy to be respected and rules of informed consent to be observed. They also expect EHRs to be protected from hackers and their family doctor to have access to their EHR. Some patients wanted access to their EHRs because of errors they came across in the health records.

A study was carried out in a group practice in London, UK to identify potential impacts of patient access to their EHRs (Honeyman, A., Cox, B., & Fisher, B. (2005). Of the 109 patients selected, 80 were interested in seeing their EHR, 78 were either 'not' or 'a little' concerned about security of their PHI. 75% responded that their having access to their EHR would improve the relationship with their doctor.

In a UK study whose aim was to find the extent to which patients would allow their EHR to be shared on a national database, of the thirty-one patients recruited in a group practice, five patients identified information they would not want shared – pregnancy, contraception, sexual health and mental health (Powell, J., Fitton, R., & Fitton, C. (2006).

A questionnaire survey of adult primary-care patients was conducted in five clinics in New Zealand (Whiddett, R., Hunter, I., Engelbrecht, J., & Handy, J. (2006). Of the two hundred respondents, sharing attitude of patients regarding their PHI was influenced by the identity of the recipient, level of anonymity, and type of information. Patients were generally willing to have their PHI shared among doctors but were less willing if it was between other stakeholders like government agencies or researchers. The study concluded that more attention needed to be paid to ensure that patients are fully informed about information sharing procedures.

In a New Zealand study, 73% of the 300 respondents were very concerned about the security of their EHRs (Chhanabhai, P., & Holt, A. (2007). There was a strong relation between age, location, computer use, EHR knowledge and concern for privacy. The study concluded that the patient needed to be more involved in ownership and maintenance of their EHR.

A study was carried out in Ontario, Canada to determine how patients and doctors perceived the benefits and harms of sharing EHRs for patient care and in cases of secondary uses. Of the five hundred patients interviewed, more than 90% supported sharing among doctors and less than 70% agreed that de-identified PHI can be shared outside the health care circle. 58% of patients believed that benefits of EHRs were greater than risks of potential security breaches in the EHRs (Perera, G., Holbrook, A., Thabane, L., Foster, G., & Willison, D. J. (2011).

In 2011, a study was carried out in Ghana whose aim was to identify the effect, if any, that information technology (IT) would have on the doctor-patient relationship. Outcomes of the study include privacy and confidentiality of PHI to secondary users cannot be guaranteed because of the many players in the medical practice space. Longitudinal population research encroaches on PHI, often without informed consent (Norman, I. D., Aikins, M. K., & Binka, F. N. (2011).

A study was carried out in London, UK to examine patient and public views about security and privacy of EHRs. Participants were recruited from primary and secondary care settings in West London. Of the 2761 participants, 79% reported worry about the security of their PHI if it was part of a national EHR. The study concluded that there is

need for public awareness together with a need for trustworthy, secure, private health PHI sharing (Papoutsi et al., 2015).

2.4 Research Gaps

Several studies have been conducted in Europe, North America, New Zealand and US that investigated patient attitude to EHRs and no similar study had been undertaken in Kenya. Research gaps from previous studies included identification of patient goals in access control and their understanding of the ethical implications of their decisions especially in a clinical setting. Understanding what impact patient education concerning the data security measures, patient rights on access and sharing of PHI stored in their EHR would have on the decisions to exercise access control of their EHRs may go a long way in establishing trust and greater adoption of EHRs. Few studies have been carried to provide insights on what patients would be willing to share and to whom in the context of EHRs. It is not clear whether patients need incentives to participate in research through EHRs and this study aimed to shed some light on this. MedbookAfrica, a PCEHR that was being piloted in Nairobi, Kenya provided an opportunity to evaluate patient willingness to share their EHRs and sharing patterns.

2.5 Dependent Variables

The dependent variable is the variable of primary interest to the researcher. In this study, the dependent variables were three; the recipient of the health information in an EHR, sensitivity of the information in an EHR and the situation in which access or sharing of an EHR is permissible.

2.6 Independent Variable

The independent variable is the one that influences the dependent variable and is presumed to cause the variation. In this study, the independent variable is patient-controlled access to their EHR.

2.7 Conclusion

This chapter reviewed various theoretical models and their applicability in EHRs, empirical literature, research gaps and the variables in the study.



CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This chapter gives a detailed description of the research methodology that was used in this study. The chapter presents details of the research design, study population, sample and sampling procedures, description of data collection instruments, validity and reliability of instruments, data collection procedures and data analysis techniques. An explanation of the ethical considerations while conducting the study is given.

3.2 Research design

A study design is the blueprint for conducting the study and spells out the strategies that the researcher will use to develop accurate, objective and interpretative information (Brink & Wood, 1998). This study adopted a mixed study approach (Creswell, J. W., & Plano Clark, V. L. (2003); quantitative data collection and analysis techniques were used to establish statistically valid associations between perception on EHRs access control and cadre of recipient, sensitivity of PHI and clinical situation. Qualitative data was derived from in-depth face to face interviews guided by open-ended questions to establish what it means to study participants to deny or grant access to their EHR. Data collection and analysis was cross-sectional, taking a snapshot of the selected population at a particular point in time (Cohen, L., Manion, L., & Morrison, K. (2002).

3.3 Population and Sample

A population refers to any group of institutions, people or objects that have common characteristics. Sampling is the process of selecting several individuals for a study in such a way that the individuals selected represent the large group from which they were selected (Ogula, 2005).

The Kenya National Bureau of Statistics (KNBS) estimated the population in Kenya to be 46 million in 2016, of which 12 million lived in urban areas. The population of Nairobi was estimated at 5 million with an adult population of about 2.5 million. Because of budgetary and time constraints, carrying out a survey on the entire adult Nairobi population was impractical and so a sample was selected.

With a 95% confidence limit, 5% margin of error and 50% response distribution, the minimum required sample size of 384, from a population of 2.5 million, was arrived at using the formula and table below (Krejcie, R. V., & Morgan, D. W. (1970).

Fig 1: Sample size formula

$$n = \frac{X^2 * N * P * (1-P)}{(ME^2 * (N-1)) + (X^2 * P * (1-P))}$$

Where:

- n = sample size
- X² = Chi – square for the specified confidence level at 1 degree of freedom
- N = Population Size
- P = population proportion (.50 in this table)
- ME = desired Margin of Error (expressed as a proportion)

Fig 2: Sample size selection

Confidence = 95%				
Population size	Margin of Error			
	0.05	0.035	0.025	0.01
1,000,000	384	784	1,534	9,512
2,500,000	384	784	1,536	9,567
5,000,000	384	784	1,536	9,585
10,000,000	384	784	1,536	9,594
50,000,000	384	784	1,537	9,602

The sampling technique that was used for the quantitative aspect of this study was probability sampling, specifically, stratified sampling. In probability sampling, every member of the population gets an equal opportunity to be selected as a representative sample. The basis of selection was random, and the opportunity of selection was fixed and known, giving unbiased, objective results. It was stratified because the sample was created from adult patients attending five private doctor outpatient clinics in Nairobi, Kenya. The clinics were specialist clinics including ophthalmology, orthopedics, obstetrics and gynecology. The reason why these clinics were chosen was that they were clinics where MedbookAfrica, an EHRs, was being piloted and they were varied in terms of medical conditions that patients had. The research participants were over eighteen years of age and this avoided the ethical requirements of conducting research on minors, and eased data collection since parental consent was unnecessary.

Each of the five clinics was sampled on five days (one clinic on Monday, one on Tuesday, one on Wednesday, one on Thursday and one on Friday). The specific date that each clinic was visited was randomly selected during the month of February 2019. This design was used to ensure a wide array of participants' characteristics that minimised selection bias. The inclusion criteria for this study were an adult (above 18 years of age), English speaking, and Nairobi resident. The following patients who were considered vulnerable and exposed to more than minimal risk were excluded from the study: children (i.e., minors or individuals under the legal age of consent), prisoners, residents of a mental health facility or nursing home), individuals with a life-threatening illness (e.g., cancer, HIV/AIDS), individuals with a debilitating mental health condition or cognitive impairment, pregnant women, victims of traumatic events (e.g., abuse, natural disasters), individuals involved in a crisis (e.g., war, natural disaster), individuals who were not fluent in English, and elderly individuals (65 years old or older).

Since this was a mixed study, the sample for the qualitative research was derived from a random sub-set of the 384 participants. The sampling done for the qualitative aspect of this study was non-probability sampling because the basis of selection of the sub-set of the sample was arbitrary and the opportunity of selection was unknown and unspecified. The method employed was subjective, and inferences made were analytical as opposed to

statistical. The qualitative aspect of this study aimed to identify recurrent themes relating to the participants' understanding of the ethical implications of denying or giving access to their EHR. In-depth face-to-face interviews were conducted until theoretical saturation was reached; theoretical saturation was taken to mean that any additional data was not going to add to the development of the themes (Hancock, B., Ockleford, E., & Windridge, K. (2001).

The principal investigator and research assistants were not liable for any health issues, physical or psychological, which may have arisen during the data collection process.

3.4 Data Collection Methods

The researcher obtained all the necessary documents prior to commencing data collection. After getting ethical approval from Strathmore University, the researcher trained research assistants for a period of one week on their role in the study. The research assistants were university graduates who were involved in the MedbookAfrica pilot; they were paid for their participation in the study.

A structured questionnaire was used to collect quantitative data and it was in written form and in English. The questionnaire was divided into two sections: the first section included questions on the study participants' socio-demographic data which was useful when investigating trends in profile. The second section contained closed-ended questions using Likert scales which were psychometric response scales that gave participants' degree of agreement with a statement and maintained the ability to measure responses quantitatively (Bertram, 2013).

Participants' anonymity was maintained and the average time to complete the questionnaire was fifteen minutes. The questionnaires were administered in the clinic waiting rooms by the researcher and research assistants with the researcher's focus being qualitative data collection while the research assistants collected quantitative data. Every patient entering the clinic was invited to take part in the study and the number of refusals recorded. After

explaining the nature of the study, willing participants who satisfied the eligibility criteria, were asked to sign the informed consent form (appendix 2).

Qualitative data collection consisted of in-depth interviews from randomly selected respondents from within the sample population. The interviews consisted of open-ended questions aimed at understanding participants' views on denying or granting access to their EHR in varying circumstances. This was carried out by the researcher.

An online replica of the questionnaire was hosted at Google Forms for respondents with insufficient time for in-person interviews. The Google questionnaire had a time limit corresponding to the final schedule of activities and went offline on data analysis commencement.

The research questions were mapped onto the data collection tools as shown below:

Research Question	Data Collection Tool	Type of question
N/A	Questionnaire Section 1	Demographic
What are patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State?	Questionnaire Section 2: Questions 1-10	Closed-ended
	Interview schedule	Open-ended
To what extent is sensitivity of EHRs linked to patient-controlled access to their EHRs?	Questionnaire Section 2: Questions 1-10	Closed-ended
	Interview schedule	Open-ended
To what extent is patient-controlled access to their EHRs situational?	Questionnaire Section 2: Questions 11-12	Closed-ended
	Interview schedule	Open-ended

3.5 Data Analysis

The statistical analysis plan involved firstly, a descriptive (univariate) analysis that described the study sample and determined proportions of participants in each response option for the outcome variables. Chi-square tests of statistical significance were used to examine significance of relation, for example perceptions regarding access control against recipient, situation and sensitivity of health information in an EHR. Chi-square tests were also used to assess whether differences found in data collected were caused by chance or were statistically significant (Cohen et al., 2002). Chi-square tests were also conducted to test whether there were significant differences in responses of participants with different socio-demographic characteristics. The social sciences significance threshold was applied with p values of less than 0.05 ($p < 0.05$) pointing towards a statistically significant relation. Quantitative data was analysed using Statistical Package for Social Sciences (SPSS). Qualitative data was analysed thematically. Data analyses findings were presented in summary tables accompanied by relevant narratives to highlight any correlations and the philosophical relevance of the conclusions.

3.6 Research Quality

The quality of the research instrument was assessed using validity and reliability. Validity is the extent to which a research instrument measures what it is supposed to measure while reliability is the ability of a research instrument to consistently measure characteristics of interest over time (Mugenda, O. M., & Mugenda, A. G. (1999). Face validity is a test to check whether the research instrument “appears, at face value, to test what it is designed to test” (Cohen et al., 2002). Face validity was carried out by administering the questionnaire to two doctors, who were professional colleagues of the researcher and a lecturer at Strathmore University. Content validity was undertaken prior to data collection by two academic experts from Strathmore University, with the requisite knowledge, to ensure proper coverage and representation of questionnaire content in relation to the research

topic, such that the instrument “fairly samples the class or fields of the situations or subject matter in question” (Cohen et al., 2002).

Reliability is the degree to which a research instrument yields consistent results (Mugenda, O. M., & Mugenda, A. G. (1999). To ensure internal reliability of test scores, a Cronbach’s alpha test was run on Statistical Package for Social Sciences (SPSS). A value of 0.7 or higher was accepted for this study; for this study the Cronbach’s alpha test was 0.78.

No. of items	14
Sum of item variances	14.6682
Variance of Total Scores	53.1827
Cronbach's α	0.779899

3.7 Ethical considerations

The researcher obtained ethical approval to conduct the study from Strathmore University’s Institutional Review Board (IRB) and National Commission for Science, Technology and Innovation (NACOSTI). The researcher sought consent from the doctors in the clinics to carry out the study in their clinics after explaining the purpose of the study and inclusion and exclusion criteria. Doctors are trained to recognize vulnerable populations such as minors, patients with impaired mental status, patients with a language barrier, patients who are physically unable to participate because they are too ill to respond etc. Patients who satisfied the inclusion criteria and were not excluded based on the exclusion criteria were included in the study.

The researcher ensured voluntary participation, without any incentives, of all study participants through informed consent and that all data obtained remained anonymous and confidential and used solely for the purposes of the study. This was explained clearly to the study participants and captured in the consent form. The risks and benefits of participating in the study were stated explicitly in the consent form and explained clearly to study participants. It was explained to the study participants that participation in the

study was optional and they were free to withdraw at any time. Research assistants were trained on ethical standards that they had to adhere to during the study.

The study participants were over eighteen years of age to avoid ethical requirements of conducting research on minors, and to ease data collection since parental consent was unnecessary. Data from study participants who had previously given consent and later chose to withdraw was not included in the final report. Study participants were provided with the contacts of the researcher and Strathmore University Institution Review Board in case they needed any further clarification about the study or chose to withdraw later.

The principal investigator and researcher assistants were not liable for any health issues, physical or psychological, which may have arisen during the data collection process.

3.8 Conclusion

This chapter covered the research design, the target population, sample selection, data collection methods, steps that ensured research quality, data analysis process and the ethical considerations in this study. In the following chapter, the study findings are presented in tables and figures together with the researcher's narration which provide a link between the conclusions arrived at and their ethical relevance.

CHAPTER 4: PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction

This chapter presents the research findings that relate to the research questions using the data collected from the questionnaires and interviews. The summaries of the research findings are presented in frequencies and percentages. This is followed by an analysis of the data comparing and relating responses from the close-ended questions in the questionnaires and the information gathered from the in-depth interviews.

4.2 Demographics

The target sample size was 384 and 394 participants were enrolled in the study with a response rate of 99% probably because most of the participants were in the waiting rooms of doctors' clinics and had adequate time to understand the study requirements and give their responses.

As shown in Figure 4.1 below, 46% of the participants were male while 54% were female. This reflected the 2016 Male: Female ratio in Kenya of 98:100 according to Kenya National Bureau of Statistics (KNBS).

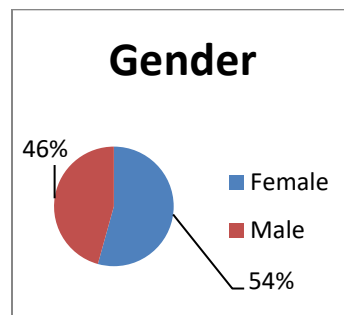


Fig 4.1 Gender distribution

Majority of the participants (54%) were between 18 and 30 years of age while 30% of the participants were between 31 and 45 years of age as shown in Figure 4.2 below. This reflected the KNBS estimate that 80% of the Kenyan population was younger than 35 years of age.

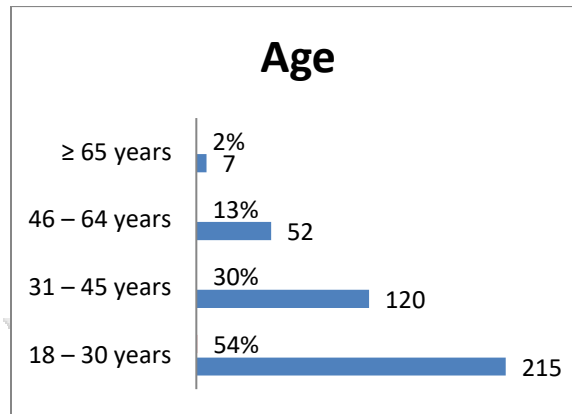


Fig 4.2 Age distribution

22% of the participants responded that their health status was very good while 69% of the participants responded that their health status was good. This finding compares well with the 2014 Kenya Demographic and Health Survey (KDHS) finding that 14% of women and 18 % of men were likely to die between exact ages 15 and 50. Because majority of the participants were between 18 and 45 years of age, it may explain why the response to health status was good or very good for 91% of the participants as shown in Figure 4.3 below.

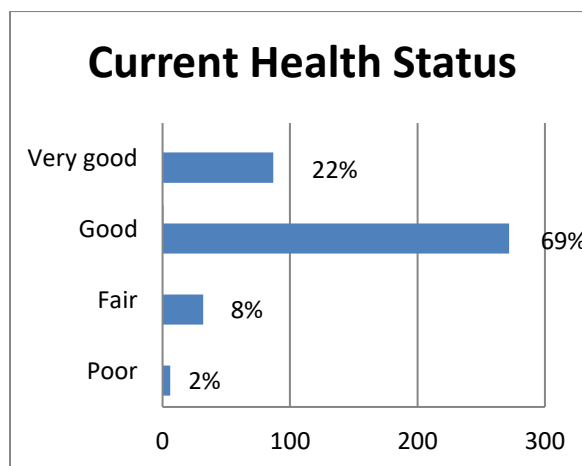


Fig 4.3 Current Health Status Distribution

87.6% of the participants had a college or university level education as shown in Figure 4.4 below. This may be explained by the fact that the sample was taken from patients attending private doctors' clinics in the capital city, Nairobi.

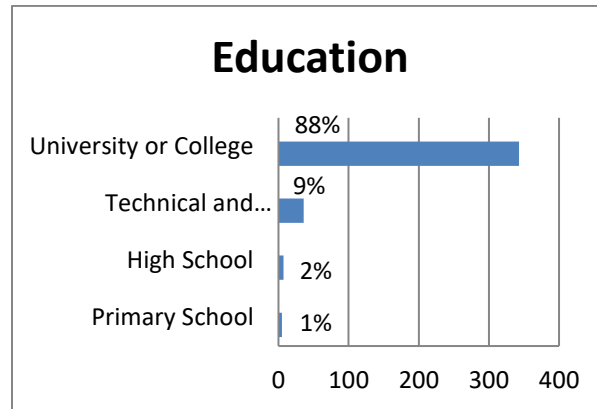


Fig 4.4 Education distribution

67% of the participants had a household income of Ksh 50,000 and above per month as shown in Figure 4.5 below. This may explain why they were able to afford to visit private doctor clinics for their medical needs.

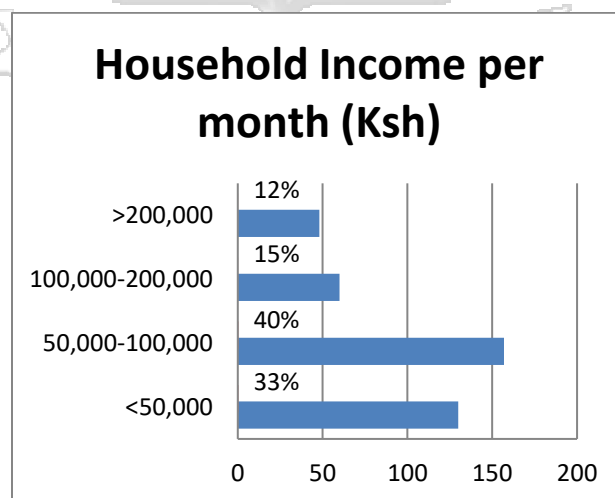


Fig 4.5 Household Income Distribution

Majority of the participants had computer experience (98.2%) and used the Internet daily (93.4%) as shown in Figures 4.6 and 4.7 on the following page. This corresponds to the Communications Authority of Kenya (CAK) January 2018 findings which put Internet penetration in Kenya at 112%, translating to 51m users. CAK also reported that Kenya is leading globally in share of internet traffic (83%). This was attributed to Kenya's high smartphone penetration which stood at 41 million, with a reach of 90.4% of the adult population.

88% of the participants in our study had a university degree and 67% had a monthly household income of Ksh 50,000 and above. This may explain their computer experience and Internet usage.

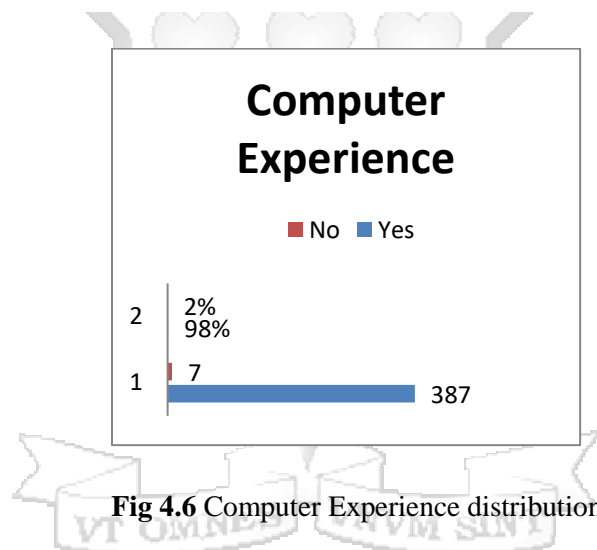


Fig 4.6 Computer Experience distribution

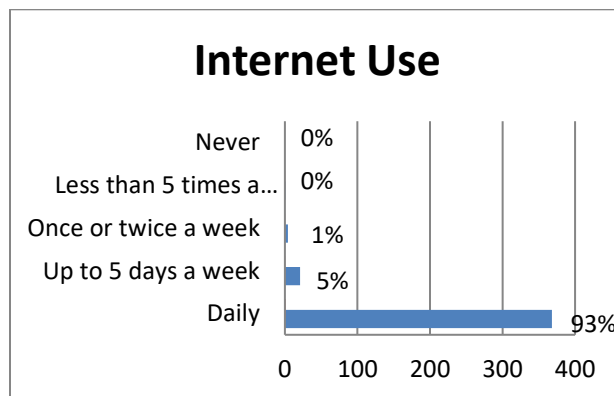


Fig 4.7 Internet Use

4.3 Findings from the questionnaire

The first research question was to identify patient perspectives on access control to their EHRs by doctors, family, researchers and State. Majority of participants (>70%) agreed that they would want to grant or deny access to their EHR irrespective of the recipient. The second research question was to identify the extent to which sensitivity of EHRs may be linked to patient controlled access to their EHRs. The vast majority of participants agreed that they should have the right to grant or deny access to their EHR irrespective of the sensitivity of the EHR.

72% of the participants agreed that they should have the right to grant or deny their doctor access to their less sensitive EHR (Figure 4.8 below) while 75% agreed that they should have a right to grant or deny their doctors access to their more sensitive EHR (Figure 4.9 below).

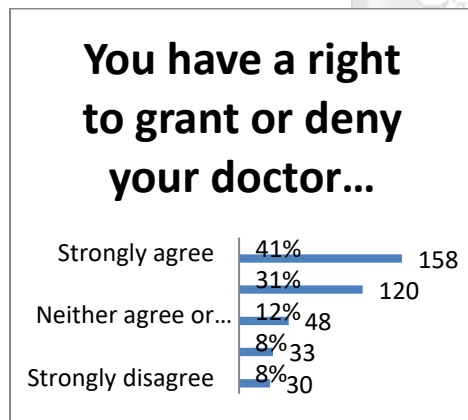


Fig 4.8 Doctor access to less sensitive EHR

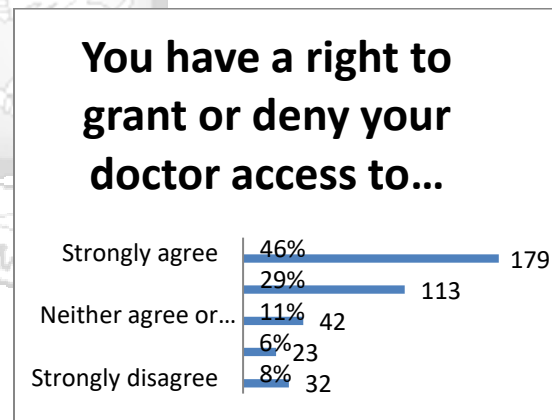


Fig 4.9 Doctor access to more sensitive EHR

73% of the participants agreed that they should have the right to grant or deny their spouse access to their less sensitive EHR (Figure 4.10 below) and a similar number (73%) agreed that they should have a right to grant or deny their spouse access to their more sensitive EHR (Figure 4.11 below).

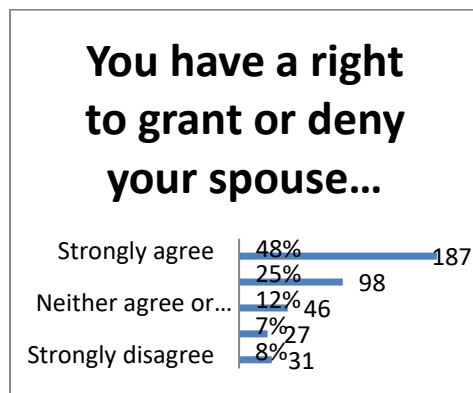


Fig. 4.10 Spouse access to less sensitive EHR

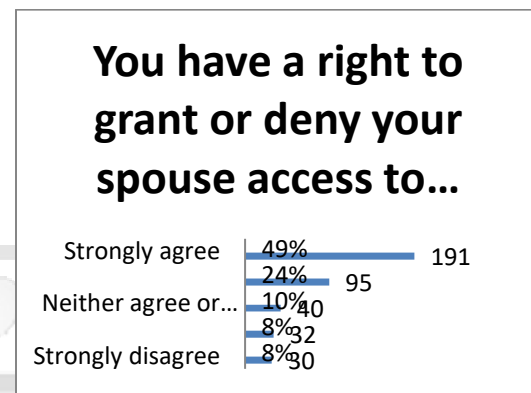


Fig 4.11 Spouse access to more sensitive EHR

90% of the participants agreed that they should have the right to access their child's less sensitive EHR (Figure 4.12 below) and 89% agreed that they should have a right to access their child's more sensitive EHR (Figure 4.13 below).

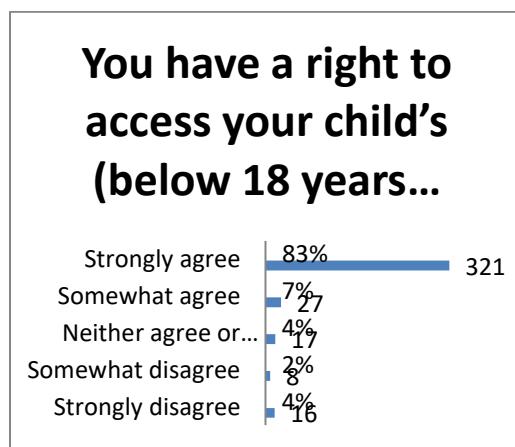


Fig. 4.12 Access to child's less sensitive EHR

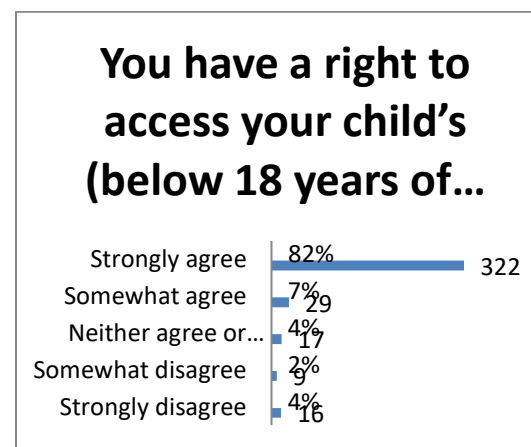


Fig 4.13 Access to child's more sensitive EHR

61% of the participants agreed that they should have the right to grant or deny the State access to their less sensitive EHR (Figure 4.14 below) while 60% agreed that they should have a right to grant or deny the State access to their more sensitive EHR (Figure 4.15 below).

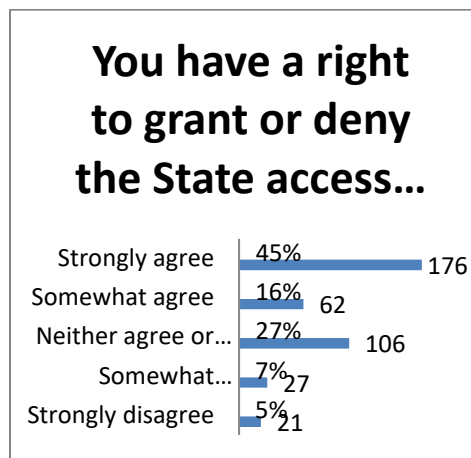


Fig 4.14 State access to less sensitive EHR

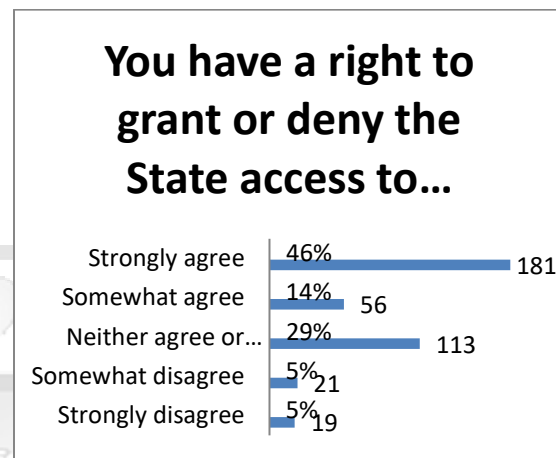


Fig 4.15 State access to more sensitive EHR

75% of the participants agreed that they should have the right to grant or deny a researcher access to their less sensitive EHR (Figure 4.16 below) while 77% agreed that they should have a right to grant or deny a researcher access to their more sensitive EHR (Figure 4.17 below).

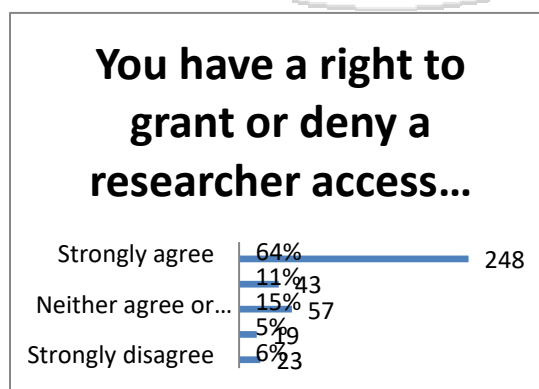


Fig 4.16 Researcher access to less sensitive EHR

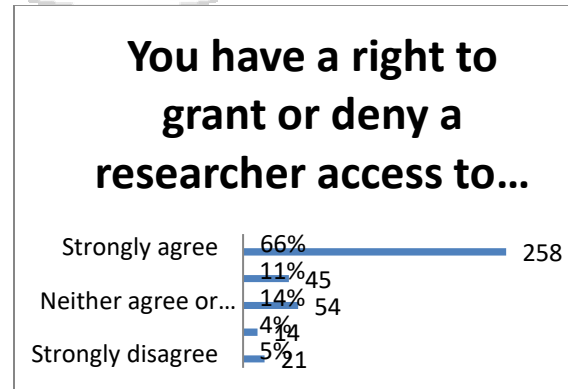


Fig 4.17 Researcher access to more sensitive EHR

The third research question was to investigate the extent to which different situations may affect patients' perspective on access to their EHRs. 56% of the participants responded that

the State had no right to access their record, without their consent even if they had a notifiable disease while only 19% agreed that they had no right to restrict access to their EHR if they had a notifiable disease (Figure 4.18 below).

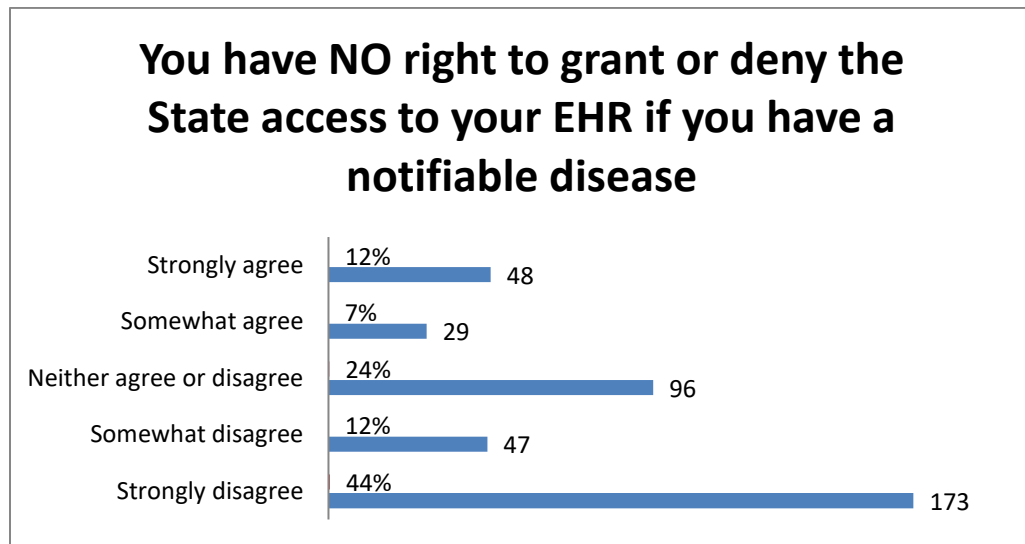


Figure 4.18 State Access if notifiable disease

Majority of the participants agreed that a patient's record should be accessible in case of an emergency (92%) (Figure 4.19 below), incapacitation (88%) (Figure 4.20) or death (81%) (Figure 4.21).

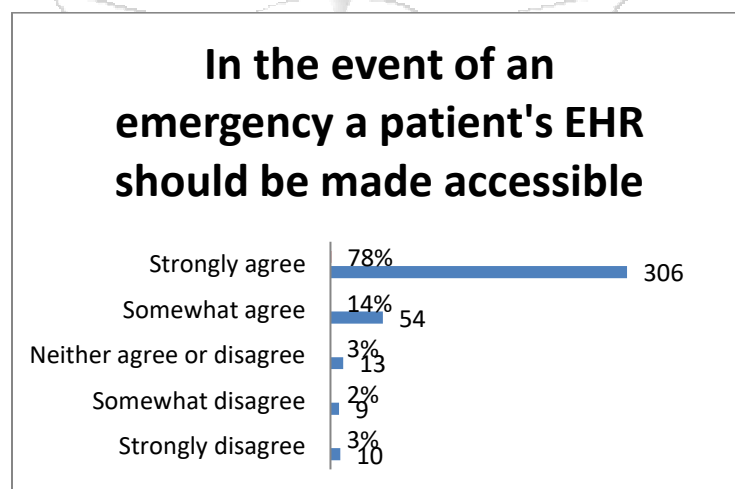


Figure 4.19 Access to EHR in emergency

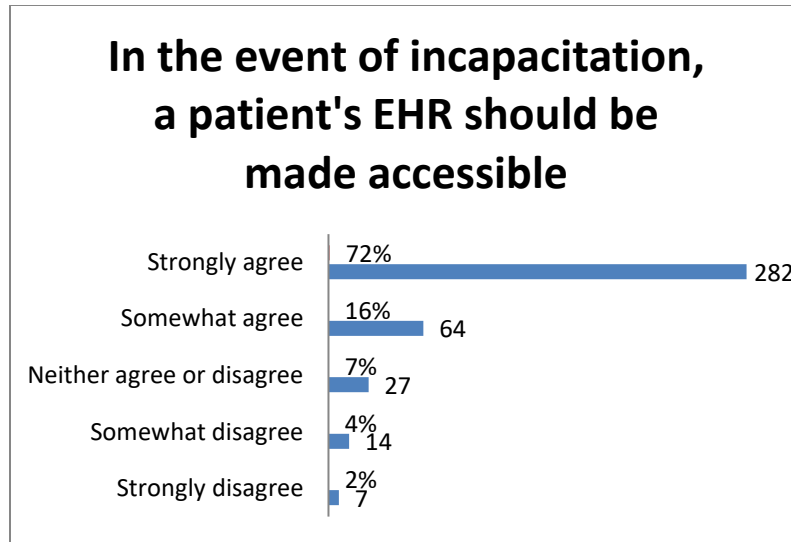


Figure 4.20 Access to EHR in incapacitaion

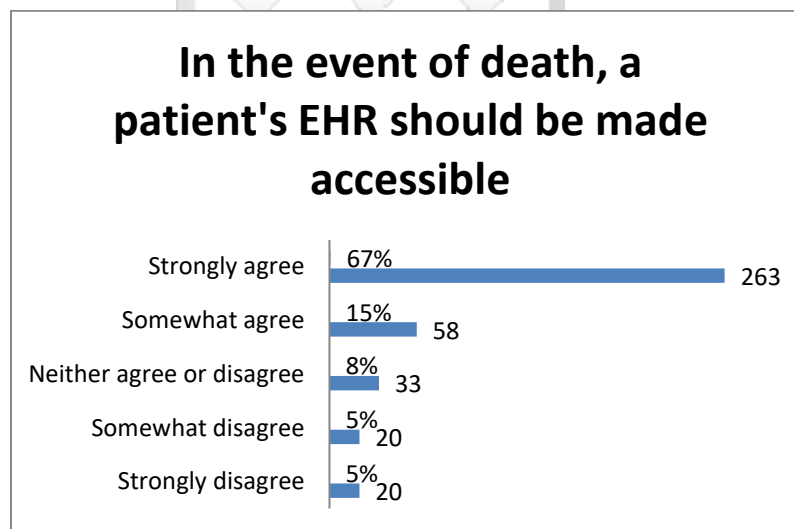


Figure 4.21 Access to EHR in death

The Chi-Square test was used to carry out inferential statistics because it is the most appropriate test to compare many categorical independent variables with one dependent categorical variable. The following were found to have statistical significance ($p < 0.05$), as shown in Table 4.1 below.

Table 4.1 Statistically significant Chi-Square test results

Demographic characteristic	Variable	<i>P</i> value
Age	Access control with a spouse	0.028
Age	Access control with a researcher	0.038
Household income	Access control with a doctor	0.018
	Access control with a spouse	0.006
Health status	Access control with a doctor	0.011
	Access control with a spouse	0.003
	Access control with State	0.010
	Access control with a researcher	0.009
	Access control if notifiable disease diagnosed	0.020

Age was a statistically significant variable when it came to access control and a spouse or researcher. This may be due to the fact that the vast majority of the respondents were younger than while household income was statistically significant for access control for doctors and spouses. Health status was statistically significant for access control for doctors, spouse, State, researcher and incase one had a notifiable disease. The Chi-Square test did not yield any statistical significance between gender and internet use and participant responses.

4.4 Interview findings

Interviews were conducted on thirteen (13) participants to identify themes and gain useful insights in patient perspectives on the ethical implications of them controlling access to their electronic health records. Thematic analysis was used as it is a suitable tool to achieve this end.

Participants were asked whether they had a regular medical doctor or medical facility that they or their family member visited whenever they were unwell. 100% of the participants responded in the affirmative. The second interview question was to find out how their medical records had been stored and 100% percent of the participants responded that their records had been stored as hard copies in files that were kept at the clinic. The third question in the interview was to ascertain whether any of the participants had ever lost their medical records and 100% responded that they had not.

The fourth question in the interview was whether the participants felt that electronic health records are secure. They all answered yes although with slightly different explanations – seven (7) said that electronic records cannot get lost, three (3) said they cannot get damaged or destroyed, two (2) said yes but expressed concern about hacking and one (1) said because they are always available.

The fifth question was whether the participants felt that their records could be accessed by some people. All the participants responded yes although with slightly different examples and explanations. Three (3) of the participants gave situations in which some people would

be able to access their records but did specify the recipient. The situations were emergencies and incapacitation – “*they would know how to handle me in case I am incapacitated*”. Nine (9) of the participants specified the recipient(s) and indicated the reason: the doctor was one person that they felt should be able to access their records to assist in “*giving treatment*”, “*to see my history and administer treatment*”, “*to understand my treatment*”. Three (3) mentioned family members together with the doctor as possible recipients and only one specified that the family member must be a close family member but did give a reason or a situation. Of the participants interviewed, family members and a doctor were people that they felt should have access to their health record to assist in their treatment and especially in emergency situations.

The sixth interview question was whether there would be consequences if the EHR was accessed without the participant’s knowledge or permission. Ten (10) of the thirteen (13) respondents said that a consequence would be “*malicious intent*” or use of the information for the “*wrong reasons*”. One (1) of the ten (10) went on to give an example of malice and said it could lead to “*loss of their job*”. Three (3) answered that it would be a “*privacy violation*”. This has a philosophical underpinning in respect for patient autonomy by respecting their records’ privacy and confidentiality. There is also an Aristotelian virtue ethic philosophical underpinning in the desire of their human good not being violated through malice.

The seventh interview question was what consequences can arise when the participant denies access to their EHR. Six respondents said that a consequence would be “lack of proper treatment in emergency situations” while three respondents said “lack of proper treatment if I am incapacitated”. Three respondents said it may lead to “lack of proper treatment” and did not specify in which situations while one respondent said “it would lead to a poor understanding of my medical condition”. The philosophical underpinnings are deontological in the principle of beneficence and nonmaleficence and Aristotelian in the pursuit of eudaimonia by pursuing the human good.

4.5 Conclusion

This chapter presented the research findings both from the closed-ended questions in the questionnaire and the interviews. A vast majority of patients agreed that they have the right to grant or deny access to their EHR irrespective of the recipient or sensitivity. A vast majority also agree that in emergencies, incapacitation or death, their health record should be made accessible. In the interviews it become clear that the recipients of the health record in case of emergency or incapacitation should be limited to family members or their doctor. The interviews also revealed that patients generally perceive their health records to be safe if stored electronically.



CHAPTER 5: DISCUSSION

5.1 Introduction

This chapter presents a discussion of the research findings using the research questions as a guide. It provides an explanation of the findings and compares them with existing knowledge in the subject. Any links between existing knowledge and the research findings are explained.

5.2 Access control and recipient

The first objective of this study was to identify patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State. The research findings were that majority of the patients would want to control access to their EHR: doctor (75%), spouse (73%), State (60%) and researcher (77%).

A New Zealand study found that 75% of patients would be willing to share nonsensitive personal information in their EHR with a doctor or nurse and 70% agreed to share sensitive data (Whiddett et al., 2006). In a study carried out in the United Kingdom (UK), five out of thirty patients (16.7%) did not want their sensitive health records available on a national database (Powell et al., 2006). In a study carried out in the United States of America (U.S), Indiana, it was found that 78% of patients would share highly sensitive information with their primary care physicians while 95% would share nonsensitive items (Caine, K., & Hanania, R. (2012).

It should be noted that in our study, doctor as recipient did not distinguish between primary physician and other medical providers such as specialists, emergency medical providers, nurses, home-care or rehabilitation therapists. In the U.S study (Caine, K., & Hanania, R. (2012), this distinction was made and findings were that participants' willingness to share sensitive information with medical providers other than their primary physician was more guarded.

In the interview section of our study, an enquiry was made as to whether the participants felt that their records could be accessed by some people. All the participants responded yes; close family members and their doctor were people that they felt should have access to their health records to assist in treatment and especially in emergency situations. The participants went ahead to emphasise that the doctor should be their family doctor or primary physician. It seemed clear that the respondents understood that the quality of care that their health care providers could provide depended on their ability to access the appropriate clinical information at the appropriate time and this can help them make the right clinical decisions that would ultimately lead to better outcomes.

The knowledge that a patient may have access to their health record may improve documentation on the part of the doctor but full access may, on the other hand, challenge the doctor's ability to include sensitive information in the patient's record (for example, mental illness, sexual history, substance abuse etc). If valuable information is withheld by patient or doctor, the patient-doctor relationship remains fractured. The moral commitment inherent in the patient-doctor covenant must be restored and protected and trust regained (Sulmasy, 2017).

In our study, findings reveal that patients agree that they should grant or deny access also to spouse and State. From a public health perspective, this may have ethical implications especially in conditions such as communicable diseases. In Kenya, doctors are required by law to report specific communicable diseases or industrially related disease as governed by the Public Health Act (Cap 242).

5.3 Access control and sensitivity of EHR

The second objective of this study was to identify the extent to which sensitivity of EHRs may be linked to patient-controlled access to their EHRs. Majority of the patients in this study (>70%) responded that they would want to control access to their EHR irrespective of the sensitivity. This differed slightly from previous studies that indicated a higher

percentage of patients willing to share less sensitive EHRs with recipients as compared to more sensitive EHRs. This was shown in the U.S study that demonstrated 95% of patients willing to share nonsensitive items as compared to 76% for highly sensitive items with their primary physician (Caine, K., & Hanania, R. (2012).

The findings in our study may be explained by the fact that the patients were being questioned in their doctor's clinics and they might have had an increased comfort level irrespective of the difference in sensitivity of their health record. It is further supported by the responses in the interviews where most patients were willing to have their records accessed by their doctors in cases of emergency or incapacitation. It seems that denying access is not related to sensitivity of the record probably because the patients felt that it would be in their benefit in terms of treatment outcomes if the doctor and family members had access to their records in emergencies or incapacitation.

In the interview, the participants were asked whether they felt that their records were stored securely. It is worth noting that all the participants interviewed had their health records stored as hard copies in their doctor's clinics and this may explain their lack of distinction of sensitivity when it came to granting access to their record.

5.4 Access control and circumstances

The third objective of this study was to investigate the extent to which different situations may affect patients' perspective on access to their EHRs. A vast majority of the participants in this study agreed that a patient's record should be accessible in case of an emergency (92%), incapacitation (88%) or death (81%). In the interview responses, the explanation for this was that denying access to a family member or doctor in such situations may have a detrimental impact on their overall health outcomes. These responses demonstrate that the patients agree with the doctors' need to practice the principle of beneficence with its philosophical underpinning in deontological ethics. Additionally, the patients' responses demonstrate Aristotle's virtue ethics in which the patient chooses, using reason, to accept access to their record by a doctor for their own good (Nic. Eth. 10.6). The doctor can do his duty but not only because it is his duty but also because it is good and makes the doctor

good. And by so doing, the doctor adds to the good of the patient because health is a human good. Participants agreed that in certain situations, such as incapacitation or emergencies, their autonomy can be overridden for their own good.

5.5 Access by the State in case of notifiable diseases

The third objective of this study was to investigate the extent to which different situations may affect patients' perspective on access to their EHRs. 56% of the participants responded that the State had no right to access their record, without their consent even if they had a notifiable disease while only 19% agreed that they had no right to restrict access to their EHR if they had a notifiable disease. In the U.S study, less than 10% of the participants were willing to share highly sensitive health information with the State (Caine, K., & Hanania, R. (2012).

5.6 Consequences of health records being accessed without knowledge or permission

In the interview responses, the need for informed consent was universally expressed. The vast majority of respondents singled out malicious intent as a possible consequence with one respondent expressly saying that it may lead to their loss of a job. Three respondents said that it would violate their privacy but did not specify a specific consequence of this privacy violation.

In an Irish mixed-methods study, 89.5% of participants agreed that their primary physician can share their EHR with researchers without their permission (Papoutsis et al., 2015). The difference between our study findings, in which informed consent was considered a requirement and the Irish study where primary physicians could share health information without consent, could be attributed to a difference in socio-demographic characteristics of the respondents.

Violation of patient autonomy may undermine the patient's humanity and disrespect their ability for reason and self-determination. Ethical frameworks in EHRs vary depending on

the 'lens' one is using; a legal 'lens' states that an EHR does not create a new legal situation but reinforces an existing one. There are three ethical arguments against obtaining explicit informed consent: first, a utilitarian argument that says that it take too much time and money. Secondly, a public interest argument that says it is in everybody's healthcare and security interest if all records were held in a national database. Thirdly, a paternalistic argument that says people may not be aware of their real values or interests and may erroneously prioritize their privacy over their health.

Patient autonomy must be balanced against public health (Sutrop, 2011).

5.7 Concern about security

In the interview section of our study, participants were asked whether they felt that health records stored electronically were secure. They all answered yes although with slightly different explanations – seven (7) said that electronic records cannot get lost, three (3) said they cannot get damaged or destroyed, two (2) said yes but expressed concern about hacking and one (1) said because they are always available.

In 2015, a UK study that looked into patient and public views about security and privacy of EHRs revealed that patients were concerned about unauthorised access, commercial exploitation and lack of accountability (Papoutsi et al., 2015). Large U.S and Canadian surveys revealed that two-thirds of adults were worried about the security and privacy of their EHRs (Papoutsi et al., 2015). It should be noted that these studies wanted to evaluate the views but based on a national database rollout. This study did not explicitly ask about a national database scenario but their general views about electronic storage of their health records as opposed to other storage systems. The respondents in our study may have compared the different storage methods but limited to their private doctor's office.

5.8 Statistically significant socio-demographic characteristics

Using the chi-square test, age was a statistically significant variable when it came to access control and a spouse or researcher while household income was statistically significant for

access control for doctors and spouses. Health status was statistically significant for access control for doctors, spouse, State, researcher and incase one had a notifiable disease.

More than half (54%) of the participants in our study were between 18 and 30 years of age. Since the marital status was not sought, it can be assumed that majority of the respondents were unmarried and may have given theoretical answers concerning access control and a spouse. It is not clear whether the answers may have been different if their marital status was ascertained but is clear that the vast majority of the respondents, being in the younger age group, wanted to exercise access control in the categories of spouse and researcher. This may reflect the younger generations' modern view of autonomy.

A higher household income was found to be statistically significant. This could be explained by the fact that those with a higher income may feel more empowered to make certain choices about their lives than those who have a lower income.

Health status was statistically significant too. This could be influenced by the general health status of most of the respondents whereby 91% felt that they were in good or very good health. This could also be influenced by the finding that the majority of the respondents were below 45 years of age (84%). With age and good health on their side, majority of the respondents may have felt a greater need to exercise autonomy than an older, more vulnerable respondent.

5.9 Philosophical relevance

Principlism, with its philosophical underpinning in deontological ethics, an ethics of duty, aims to establish rules of action. Regarding EHRs, a deontological approach protects privacy and confidentiality out of “*respect for persons*, grounded in the fundamental principle of *autonomy*” (Secker, 1999). A doctor must practice the four principles: respect for autonomy, nonmaleficence, beneficence and justice in discharging his duties towards a patient. Virtue ethics, an ethics of the good, has its roots in the Hippocratic oath. A virtuous doctor must be guided by his obligation to work for a good outcome in the patient-doctor encounter – that which benefits the patient and does him no harm. Virtue and duty are

motivators for action, but virtue is more than a stimulus for right action; it is an integral part of character and helps in making right decisions based on what is good (Vizcarrondo, 2012).

Participants in our study had no problem if close family members or their primary doctor had access without their explicit consent if they were incapacitated or were in an emergency. In the event of an emergency or incapacitation, the doctor is bound by duty and virtue to provide for the good of the patient; to do everything possible, in accordance with medical professional ethics to save the life of the patient (Vizcarrondo, 2012). There is a case for overriding autonomy and practising beneficence, nonmaleficence and virtue and the participants agreed that they would not want their records withheld in those situations because their well being was paramount compared to an apparent infringement on their autonomy.

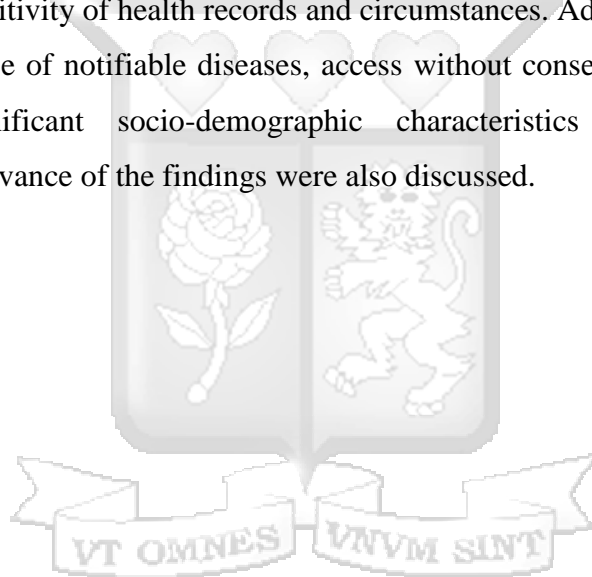
Aristotle considers “the State to be prior to the family and to the individual, since the whole is of necessity prior to the part” (Barnes, J. (Ed.). (1995). The implication of this is that in case of conflict between the individual good and the common good, the common good would be a higher good. For Aristotle, the common good is “a good proper to, and attainable only by the community, yet individually shared by its members” (Dupre, 1993). According to Aristotle, the common good is not a sum of individual goods; this would be a utilitarian argument. A requirement of attaining this common good is virtuous citizens, especially justice (Sutrop, 2011).

The modern view is one of man as self interested and only interacting with other men through contracts to achieve a selfish goal. Communitarian ethicists make an argument for public health having an ‘ethical seat’ above individual rights and autonomy. Regarding research, their argument is based on a sense of duty grounded in solidarity with fellow man, that should allow people’s health information to be accessed with ‘open consent’. A utilitarian argument in support of this approach is that it is for maximum happiness for maximum number of people and should outweigh right to privacy and autonomy (Sutrop, 2011).

However, a communitarian argument can restrict individual autonomy to a detrimental level that can lead to abandoning individual freedom to promote the common good whose meaning may be misguided. So, there is a case for adopting Aristotle's view of the common good which promotes the growth of virtue among people that would simultaneously secure both individual and common good of a community.

5.10 Conclusion

This chapter discussed the research findings on participant sharing preferences with regards to recipients, sensitivity of health records and circumstances. Additionally, State access to records in the case of notifiable diseases, access without consent, security concerns and statistically significant socio-demographic characteristics were discussed. The philosophical relevance of the findings were also discussed.



CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter presents a summary of the research findings, conclusions that may be drawn from these findings, recommendations, suggestions for future research and final considerations.

6.2 Summary of research findings

This study aimed at evaluating patient perspectives on access control of Electronic Health Records (EHRs).

The study sought to answer the following research questions:

1. What are patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State?
2. To what extent is sensitivity of EHRs linked to patient-controlled access to their EHRs?
3. To what extent is patient-controlled access to their EHRs situational?

Regarding the first research question, participant responses to the closed-ended questions of the questionnaire revealed that a vast majority of participants agreed that they would want to grant or deny access to their EHR irrespective of the recipient. Approximately 73% of the participants agreed that they should have the right to grant or deny their doctor and spouse access to their EHR. 90% of the participants agreed that they should have access to their child's (under 18 years of age) record while 61% agreed that they should have the right to grant or deny the State access to their record. A further 75% agreed that they should have the right to grant or deny a researcher access to their record.

The in-depth interviews revealed that a vast majority of the respondents felt that their doctor and close family members should have a right to access their health records because this would assist in overall management.

Regarding the second research question, participant responses to the closed-ended questions of the questionnaire revealed that a vast majority of participants agreed that they would want to grant or deny access to their EHR irrespective of the sensitivity. The numbers were very similar when it came to granting or denying access based on sensitivity: for doctors (75% agreed for more sensitive and 72% for less sensitive), for spouse (73% for both levels of sensitivity), for child (90% for both levels of sensitivity), for State (60% for more sensitive and 61% for less sensitive) and for researchers (77% for more sensitive and 75% for less sensitive).

Regarding the third research question, a vast majority of the participants agreed that a patient's record should be accessible in case of an emergency (92%), incapacitation (88%) or death (81%). 56% of the participants responded that the State had no right to access their record, without their consent even if they had a notifiable disease while only 19% agreed that they had no right to restrict access to their EHR if they had a notifiable disease.

The in-depth interviews revealed that a vast majority of the respondents felt that their EHRs should be accessible in the case of an emergency or incapacitation, especially by their doctor or close family member because that may assist in shedding light on any underlying disorder and improve treatment outcomes.

6.3 Conclusions

A vast majority of patients agreed that they have the right to grant or deny access to their EHR irrespective of the recipient or sensitivity. A vast majority also agree that in emergencies, incapacitation or death, their health record should be made accessible. In the interviews it became clear that the recipients of the health record in case of emergency or incapacitation should be limited to close family members or primary doctor. The interviews also revealed that patients generally perceive their health records to be safe if stored electronically.

6.4 Recommendations

The first research question was what are patient perspectives on access control to their Electronic Health Records (EHRs) by doctors, family, researchers and State? A vast majority of participants agreed that they would want to grant or deny access to their EHR irrespective of the recipient. A vast majority of the respondents also felt that their doctor and close family members should have a right to access their health records because this would assist in overall management. A recommendation, based on the research findings, is that a level of informed consent needs to be factored in during EHR design. This would protect patient autonomy to some extent and conditions when this can be overridden can be agreed upon by all stakeholders. An open dialogue between patients and health care providers is needed to balance respect for patient autonomy and the health care provider's need for patient information to provide good quality care. Patients must accept that doctors must have access to their health records, in some cases without explicit consent, to provide the best quality care. Patients and health care providers need to agree about what health information should be accessible, by whom and in which circumstances.

The second research question was to what extent is sensitivity of EHRs linked to patient-controlled access to their EHRs? A vast majority of participants agreed that they would want to grant or deny access to their EHR irrespective of the sensitivity. A recommendation, based on the research findings, is that a consensus should be reached between the various stakeholders that determines the cadre of health care professionals who may have full access to patient health records for example primary doctors or emergency specialists.

The third research question was to what extent is patient-controlled access to their EHRs situational? A vast majority of the participants agreed that a patient's record should be accessible in case of an emergency, incapacitation or death especially by their doctor or a close family member because that may assist in shedding light on any underlying disorder and improve treatment outcomes. A recommendation would be that situations can also be agreed upon, by the stakeholders, such as emergencies or incapacitation, in which primary

doctors and emergency care specialists can have full access to a patient's health record, for the patient's benefit.

Also connected to the third research question our study found that 56% of the participants responded that the State had no right to access their record, without their consent even if they had a notifiable disease while only 19% agreed that they had no right to restrict access to their EHR if they had a notifiable disease. A recommendation would be that conditions for the exercise of individual autonomy must be created because autonomy remains important even if public health is prioritized. Patients need to be educated that in cases of notifiable infections, their right to exercise autonomy by granting explicit consent may have to be overridden by the State for public health interest.

Finally, it must be appreciated that achieving the balance between autonomy and the common good is a delicate one and the various stakeholders need to exercise practical wisdom to respect the dignity of the human person.

6.5 Suggestions for future research

Further research is needed to evaluate doctors' perspectives on patient-controlled access to their EHR. Since doctors are integral in health care provision, their acceptance of patient autonomy is necessary. Patients too need to evaluate the ethical implications of them denying health professional access to their health records. This can guide both doctors and patients in reaching a middle ground which is acceptable to both in health information sharing that is most beneficial to the patient-doctor relationship.

Further research is needed to evaluate patient preference for access control with different cadres of health professionals. This study focused on doctors as one of the recipients but did not distinguish between different cadres of health professionals. Understand sharing preferences of patients among different cadres of health care professionals may establish protocols of what data is to be shared by patients or made available to health professionals depending on their cadre.

A similar study should be carried out in an inpatient setting. This study was carried out in an outpatient setting and results in an inpatient setting may differ because of the likelihood of different, probably more serious medical conditions.

A similar study should be carried in public health care facilities. This study was carried out in private clinics and the socio-demographic characteristics of patients are likely to differ in the two settings with a possibility of different responses.

A similar study can be carried out with a wider range of specialist clinics such as Human Immunodeficiency Virus (HIV) or cancer clinics. This may give greater insight especially in sharing preferences in patients with more sensitive health records.

6.6 Final considerations

In current times, focus on rights of individuals with for example, exercise of patient autonomy in health care, must be balanced with the role of ethics that determines human relationships. ‘Modern man’ as an autonomous being must be balanced against ‘Aristotle’s man’, a social and political ‘animal’ having a telos in his pursuit of eudaimonia. Virtue ethics can be a solution in practical decision making in medicine both by the patient and the doctor, assisting the parties concerned in choosing suitable means for best possible outcomes.

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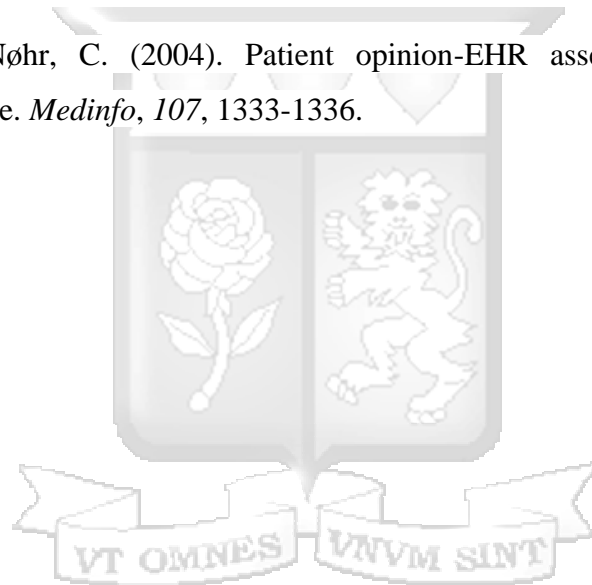
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Appendices

Appendix 1: Timeline of activities

Activity	Start	Finish
Proposal writing, defence and amendments	Jan 2018	Dec 2018
Proposal approval	Dec 2018	Dec 2018
Ethical approval and NACOSTI permit	Dec 2018	Dec 2018
Training research assistants	Dec 2018	Dec 2018
Reproduction of questionnaires	Dec 2018	Dec 2018
Data collection and analysis	Jan 2019	Feb 2019
Report writing	Mar 2019	March 2019
Presentation	April 2019	April 2019

Appendix 2: Informed Consent Form

INFORMED CONSENT FORM

TITLE OF STUDY

Patient Perspectives on Access Control of Electronic Health Records

PRINCIPAL INVESTIGATOR

Dr. Polly Okello

School of Humanities and Social Sciences (SHSS),

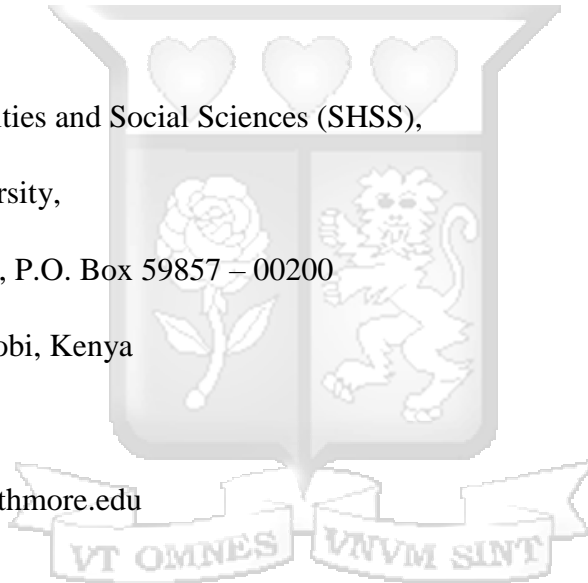
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polly.okello@strathmore.edu



PURPOSE OF THE STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to evaluate patient perspectives on access control of Electronic Health Records.

STUDY PROCEDURES

You will be required to fill out a questionnaire that will be provided by a research assistant. This should take no more than a few minutes.

RISKS

There are no foreseeable risks to you in taking part in this research. The principal investigator and researcher assistants will not be liable for any health issues, physical or psychological, which may arise during the data collection process. Any medical needs that you may need will be provided by your doctor. The research investigators are not qualified or approved to provide any medical assistance that you may require during the time of the study and in case of any medical emergency, the researchers will alert the doctor immediately. You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

BENEFITS

There will be no direct benefit to you for your participation in this study. However, we hope that the information obtained from this study may assist policy makers in ensuring ethical aspects are incorporated in EHR design, including informed consent, privacy and confidentiality of patient records.

CONFIDENTIALITY

Your responses to this questionnaire will be anonymous. Every effort will be made by the researcher to preserve your confidentiality including assigning code names/numbers for participants that will be used on all research notes and documents.

CONTACT INFORMATION

If you have questions at any time about this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Strathmore University Institution Review Board at Tel (+254) 703-034-363.

VOLUNTARY INFORMATION

Your participation in this study is voluntary. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

CONSENT

I have read, and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Researcher's signature _____ Date _____

Appendix 3: Data Collection Tools

a. Questionnaire

Thank you for taking your precious time to complete this questionnaire – which should only take a few minutes to complete. It is part of a research on patient perspectives on access control of Electronic Health Records (EHRs). This research is purely academic and the information you will provide will be treated confidentially and will be used strictly for research purposes only. Kindly mark the most suitable box next to each response. Please use the sharing preference card as a guide in answering the relevant questions.

Sharing Preference Card

Less sensitive health information	
Contact information	Address, Telephone number
Race or tribe	
Current medication	Prescribed and over the counter
Recent vital statistics	Blood Pressure, height, weight
Past unrelated medical history	Previous medical or surgical conditions
More sensitive health information	
Sexual health information	Sexual orientation, sexually transmitted infections including HIV
Mental health information	Diagnosis of a psychiatric illness, use of medication for a psychiatric illness, previous suicide attempt(s)
Substance abuse	Previous history of alcohol or drug abuse

Domestic violence	Previous history of domestic violence (reported/treated or not)
Reproductive health information	Infertility, abortion, adoption
Genetic information	Results of genetic tests History of taking a paternity test and the results History of diagnosed genetic disorders in the family
Notifiable infections	
malaria, pneumonia, diarrhoeal disease, tuberculosis, cholera, measles, meningococcal meningitis, other viral haemorrhagic fevers, plague, typhoid fever, poliomyelitis, yellow fever, neonatal tetanus, dracunculosis, leprosy	

Section 1:

Gender	Female <input type="checkbox"/> Male <input type="checkbox"/>
Age	18 – 30 years <input type="checkbox"/> 31 – 45 years <input type="checkbox"/> 46 – 64 years <input type="checkbox"/> ≥ 65 years <input type="checkbox"/>
Education	Primary school <input type="checkbox"/> High school <input type="checkbox"/> Technical and Vocational training <input type="checkbox"/> University or College <input type="checkbox"/>

Race	African	<input type="checkbox"/>
	White	<input type="checkbox"/>
	Asian	<input type="checkbox"/>
	Multiracial	<input type="checkbox"/>
	Other	<input type="checkbox"/>
Household income (Per month, Ksh)	< 50,000	<input type="checkbox"/>
	50,000 – 100,000	<input type="checkbox"/>
	100,000 – 200,000	<input type="checkbox"/>
	>200,000	<input type="checkbox"/>
Current health status	Poor	<input type="checkbox"/>
	Fair	<input type="checkbox"/>
	Good	<input type="checkbox"/>
	Very good	<input type="checkbox"/>
Computer experience	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Use of internet	Daily	<input type="checkbox"/>
	Up to 5 days a week	<input type="checkbox"/>
	Once or twice a week	<input type="checkbox"/>
	Less than 5 times in a month	<input type="checkbox"/>
	Never	<input type="checkbox"/>

Section 2:

To what extent do you agree or disagree with the following statements?

1. You have a right to grant or deny your doctor access to your less sensitive Electronic Health Record (EHR)

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. You have a right to grant or deny your doctor access to your more sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. You have a right to grant or deny your spouse access to your less sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. You have a right to grant or deny your spouse access to your more sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. You have a right to access your child's (below 18 years of age) less sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. You have a right to access your child's (below 18 years of age) more sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. You have a right to grant or deny the State access to your less sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. You have a right to grant or deny the State access to your more sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. You have a right to grant or deny a researcher access to your less sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. You have a right to grant or deny a researcher access to your more sensitive EHR

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. You have NO right to grant or deny the State access to your EHR if you have a notifiable disease

Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. In the event of an emergency, incapacitation or death, a patient's EHR should be made accessible

	Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree
Emergency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Incapacitation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Interview Schedule

Continuation from questionnaire:

1. May I take a few additional minutes of your time to conduct a brief interview to better understand some of the answers you gave in the questionnaire? Thank you.
2. The purpose of this interview is to investigate whether and to what extent it is ethical for patients to control access to all or part of their Electronic Health Record (EHR).
3. Do you have any questions before I start?

Personal experience

1. Do you have a regular medical doctor or medical facility that you or your family members visit whenever any of you is unwell?
2. How are your health records stored?
3. Have your health records ever been lost?

Body

1. Do you feel that electronically stored health records are secure? Please explain
2. Do you feel that there are some people who should have access to your health records?
 - a. If yes, why?
 - b. If no, why?
3. Are there situations in which you feel that your health records can be accessed without your knowledge or permission? If there are, please explain
4. What do you think are some consequences of your records being accessed without your knowledge or permission?
5. What do you think can be consequences of denying access to your health records?

Transition

1. Is there anything else you may want to add?
2. Do you have any questions?

Closing Thank you very much for your participation. Have a lovely day.

Appendix 4: Budget

Reproduction of questionnaire	Ksh 10,000.00
Research Assistant salaries	Ksh 75,000.00
Miscellaneous	Ksh 15,000.00
Total	Ksh 100,000.00

